REMARKS

Claims 1-6 and 8-42 were pending in the application. Claim 1 has been amended, claim 7 was previously canceled and claims 13-14 are canceled herein. Accordingly, claims 1-6 and 8-12 and 15-42 will remain pending.

No new matter has been added. Any cancellation of the claims should in no way be construed as an acquiescence to any of the Examiner's rejections and was done solely to expedite the prosecution of the application. Applicant reserves the right to pursue the claims as originally filed in this or a separate application(s).

Rejection of Claims 1-42 Under 35 USC 103(a)

The Examiner has rejected claims 1-6 and 8-42 under 35 USC 103(a) as being unpatentable over Ueno and Yano et al. in view of Troyer et al. and Schneider et al. Applicant traverses this rejection.

Claim 1, as amended and all the claims now require that there are specific minimum amounts of eicosapentaenoic acid (EPA) and docosahexaeonic acid (DHA) in the daily dose, and specific ratios of n-6 to n-3 containing oils. Certain of the claims (claim 15 and those depending therefrom) also require an oil soluble antioxidant.. In contrast, none of the references, either individually or in combination, specify doses of EPA and DHA that are as high as the doses used herein, none provide the ratios of n-6 to n-3 oils. In addition, none show use of an oil soluble antioxidant. Further, many of the claims have even more specific amounts of the EPA and DHA, as well as other materials such as n-6 fatty acids, vitamin E, and mixed tocopherols. Certain of these claims even have specific sources or amounts of each of these materials. Clearly, the invention as claimed is not obvious merely because Ueno uses fatty acid derivatives and Troyer et al. use n-3 fatty acids generally. Neither reference shows any values close to the present invention. Ueno does not give amounts for anything except prostaglandins and Troyer uses "at least about 94 mg of these three components together, and preferably contains about 235 mg of these." The three components are omega-3 fatty acids (without specifying which n-3), omega-6 fatty acids and GLA. In contrast, the presently claimed formulation uses at least 150 mg of EPA and at least 50 mg DHA in an n-3 containing oil and has an n-6 containing oil at a 1 to 3 to 3 to 1 ratio with the n-3 containing oil. Clearly, the amounts of DHA and EPA are

substantially higher in the present formulation. In fact, some of the claims require the preferred ranges of 250-350 mg DHA and 350-450 mg EPA. Values like this are not shown in the references. Further, none of the references show an oil soluble antioxidant used in the formulation. The addition of the other references do not cure these deficiencies in the art.

The instant invention is based on the identification that the combination of n-3 rich oils containing these high concentrations of DHA and EPA fatty acids with an n-6 fatty acid containing oil effectively treats dry eye, dry mouth and related conditions. DHA and EPA are fatty acids that are present in a number of oils, primarily from fish oils and certain other oils, but they are not present in all oils, and the amounts in most fish oils are relatively low. For example, Troyer uses cod liver oil for the primary n-3 source. Cod liver oil is not a good source of DHA, providing only about 127 mg/tablespoon. To reach the preferred DHA range, you would need 3 tablespoons or about 45 ml. As this is only part of the oil, no one would eat this much. In addition, that much cod liver oil would provide over 12 mg of vitamin A, a material that has been shown to cause birth defects in high doses, e.g., over 10 mg/day. Black currant seed oil has almost no EPA or DHA. Since the claims are specific to amounts of those n-3 oils (EPA and DHA), and many of the oils that do contain both DHA and EPA do not contain high levels of these fatty acids, these references do not render obvious the claimed invention.

As noted, Ueno does not teach or suggest n-3 fatty acids containing high concentrations of EPA and DHA. Rather, Ueno merely lists a number of fatty acids and there derivatives that can be used in the methods of his invention and does not provide teachings about specific combinations which are clinically effective. The oils listed in Ueno, which form the basis of the derivatives described therein, include not just DHA and EPA but also arachidonic acid, linoleic acid and other n-6 oils. There is nothing to suggest that there is anything special about DHA or EPA per se; in fact, as noted, Ueno does not use the oils themselves. Ueno does not teach the specific combination of EPA and DHA in n-3 rich oils at all. Moreover, Ueno does not teach or suggest that high concentrations of these specific fatty acids are beneficial for the treatment of dry eye and related conditions.

The secondary references cited by the Examiner, such as Yano et al., does not make up for the deficiencies of Ueno. Yano et al. teach that the combination of vitamin E and DHA can modulate cell apoptosis induced by TNF. Yano does not teach the combination of oils rich in

DHA and EPA with vitamin E or the addition of n-6 containing oils. Moreover, Yano et al. is directed to inhibiting apoptosis induced TNF. Yano et al. does not teach or suggest the use of EPA and vitamin E for the treatment of the conditions set forth in the instant claims, and therefore, even if Yano et al. did teach a combination of the claimed fatty acids with vitamin E, one of skill in the art would not think to apply these teachings to the treatment of disorders such as dry eye.

Even if Yano et al. had provided teachings related to the use of EPA and vitamin E for the treatment of dry eye, the combination of Yano et al. and Ueno would still fail to render the instant invention obvious. The instant invention is based on the identification that the combination of n-3 rich oils containing certain high concentrations of DHA and EPA fatty acids in combination with an n-6 fatty acid containing oil effectively treat dry eye and related conditions. Therefore, the combination of the teachings of Yano et al. and Ueno do not lead one of ordinary skill in the art to the claimed invention.

Adding Troyer et al. and Schneider et al. do not change the overall difference between the claimed invention and the failure of the references to disclose of the presently claimed invention. None of the references discuss the beneficial effects of a combination of DHA and EPA nor the amounts claimed in the claims as amended. There is nothing to combine the references as suggested by the Examiner but even the combination does not disclose or render obvious the amended claims.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the foregoing rejection.

CONCLUSION

In view of the above amendment, Applicants believe the pending application is in condition for allowance. If a telephone conference would expedite allowance of this application, the Examiner is urged to call the undersigned.

Dated: July 30, 2008

Respectfully submitted,

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